

### **Remarks**

Claims 1-14 and 26-31 are pending in the application.

With this amendment, claims 1, 5, 6, 9, 12, 13, 14, 26, and 30, are amended. Claim 10 is cancelled. No new claims are added.

The amendments are supported by the original specification. For example, the amendment to claims 1, 9, and 26 are supported by the specification as originally filed, e.g., at original claim 10, and elsewhere throughout the original specification.

Claims 1-9, 11-14, and 26-31 remain in the application for consideration.

Reconsideration and allowance of the claims as amended in light of the following remarks, are respectfully requested.

### **The Invention**

The claimed novel devices combine a drainage catheter with anastomosis functionality, as has not previously been done. The combined features of the device offer multiple and significant advantages over previous devices and methods for anastomosis. The combined devices provide significantly improved ease of use, especially relative to previous standard methods of anastomosis by manual suturing techniques. The devices can also improve efficacy of healing, e.g., by improving hygiene at the site of anastomosis by reducing or preventing urine contact with the anastomosis site during healing. As stated in the application:

*Advantageously, the device, including the tissue approximating structure, can be left installed during the healing process to function to allow the tissue to heal while at the same time functioning to drain urine from the bladder.*

Page 2, lines 13-15.

*Methods of the invention can use such an anastomosis device, including both a draining function and a tissue approximating function, to accomplish healing of the anastomosis, without sutures, and draining of the bladder, with the single anastomosis device and preferably without removing or replacing the device during or after the procedure until healing is complete. The anastomosis device can be installed during or after a radical prostate removal procedure, and can remain installed with the bladder-draining function and the tissue-approximating function in effect until the anastomosis is completely healed and the severed tissue, e.g., bladder and urethra, are re-connected. Thus, an advantage associated with inventive methods and devices can be that the anastomosis device performs dual functions when installed during and following an anastomosis procedure,*

*of draining the bladder and functioning as a tissue approximating structure, at the same time.*

Page 2, lines 13-15. Also:

*During use, the balloon can rest against the neck of the bladder to prevent urine from entering the neck and to prevent urine from contacting the anastomosis site. Urine at the anastomosis site has the potential to cause difficulties in healing or to cause a stricture, among other deleterious effects.*

Page 6, lines 8-16.

### **Claim Rejections - 35 USC § 102**

Claims 1-2 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Salama (U.S. Patent No. 5,306,226).

The rejection is overcome by amendment to claims 1, 9, and 26.

The Salama reference describes a device used to drain a bladder (col. 2, line 18) including a urine tube 12 having sidewalls, sidewall openings 18, and a balloon 26 formed in part by the sidewalls that may be inflated (col. 2, lines 23-29) to correspond to the shape of the inner side walls of a bladder (col. 2, lines 40-43). An anchoring collar means 36 is provided around the urine tube 12 and is placed at the outlet end of a urethra against the outside of a person's body (col. 2, lines 35-36 and 50-51). The anchoring collar means 36 frictionally engages the outer surface of the urine tube 12 and is positioned against the body at the outer end of the urethra to hold the balloon 26 in tight sealing contact with the bladder orifice and neck 38 (col. 2, lines 35-38 and col. 3, lines 18-22). No urine can leak around the urine tube 12 due to the seal the balloon 26 provides with the bladder neck 38 (col. 3, lines 23-26). Note that the collar is external to the patient's body during use.

Amended claims 1, 9 and 26, are novel in view of the Salama reference. Claims 1, 9, and 26 provide that tissue approximating structure or tissue approximating means are located at a distal end of the device. This distinguishes from Salama. See, e.g., the discussion of "distal end," in the original application at page 3:

*According to the present description, the term 'distal end' refers to a function of an anastomosis device that is inserted into a body during an anastomosis procedure and that then becomes located in the region of the bladder, urethra, urethral stump, and perineal wall.*

The feature of tissue approximating structure located at a distal end of a device is not identically shown by the Salama reference and the rejection under section 102 can be withdrawn. Rejections of claims that depend upon claims 1, 9, and 26 can also be withdrawn.

### **Claim Rejections - 35 USC § 103**

#### **Claims 3, 7-8, 12-14 and 26-31**

Claims 3, 7-8, 12-14, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salama (U.S. Patent No. 5,306,226) in view of Seiba (U.S. Publ. No. 20030229364).

#### **The Office Action Fails to Support the Rejection**

The Salama reference relates to a drainage catheter that when used, places a drainage aperture and a balloon internally, and a hydrogel collar externally at the external opening of the urethra. The external collar allows traction to be applied to the catheter to hold the balloon, located inside the bladder, against tissue of the bladder, to prevent leakage of urine from the bladder. The device is not useful for tissue approximation or anastomosis.

The Seiba reference shows a device that includes an expandable stent 10 that may be delivered using a delivery catheter 50 (paragraphs 0028, 0039). The stent 10 may include two circumferential rows of retractable needles 35, 40, that can be attached to a conduit and approximate two conduits to facilitate fluid flow and patency between the two conduits (paragraphs 0026, 0028, 0030). The delivery catheter 50 does not stay in the body, but is removed subsequent to delivery and placement of the stent 10 (paragraph 0050), with the stent remaining inside of the body. The device disclosed in Seiba, therefore, includes a stent used for tissue approximation, and a catheter to install the stent; the Seiba device does not function to seal and drain the bladder.

For clarification, the Office action misconstrues the structure shown in the Seiba reference. In specific, the Seiba reference does not show first and second tissue approximating structure “on a catheter body 220” as is an assertion found at page 3 of the Office action. The reference shows “retractable needle” structures located on an expandable stent (which is not a catheter body). The inaccuracy of this basis of rejection should be noted and corrected with regard to future consideration of the Seiba reference relative to the pending application.

Overall, the expandable stent of the Seiba reference is distinct from and as a technical matter is incompatible with the drainage catheter of Salama; the Seiba reference includes a “Delivery Catheter” that separates from the “expandable stent.” The Seiba expandable stent does not require and specifically excludes an inflatable balloon, anchoring collar means, and catheter body, as are requirements of the Salama catheter.

An approach for analyzing obviousness was recently identified in the recent Supreme Court case of *KSR, Int’l Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, slip op. (2007). In part, the Supreme Court discussed obviousness as follows:

*claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (CA Fed. 2006) (‘[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness’). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.*

*Id.*, at 14 (emphasis mine). . . .

*[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.*

*Id.*, at 14-15.

The Office action contains the conclusory assertion that: “It would have been obvious . . . to provide a tissue approximating structure, as taught by Seiba, to [the device of] Salama in order

to make the [Salama] device applicable to anastomosis using a device that facilitates fluid flow and patency of the two conduits.”

This is a legal conclusion not supported under the law or in view of the Office action and cited references.

A rejection on obviousness cannot be sustained by mere conclusory statements such as those found in the Office action, but must include some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. To the extent that the Office action offers any “reason” for making the asserted combination, the “reason” reduces down to an assertion that claim elements identified separately in the prior art, but not used together as claimed, would have been obvious “to provide” as a device with the claimed combination of features (even though the prior art did not do this):

*It would have been obvious . . . to provide a tissue approximating structure, as taught by Seiba, to [the device of] Salama in order to make the [Salama] device applicable to anastomosis using a device that facilitates fluid flow and patency of the two conduits.*

In essence, the rejection reasons that it would have been obvious to arrive at the invention, because one of skill would have wanted a device with features of the invention!

There is no other reason provided for the obviousness rejection, and the presented grounds are not sufficient to support a rejection based on obviousness. For instance, based on the applied reasoning, it is hard to imagine that anything would be patentable at all if separate features of a claim could be found separately in the prior art. The patent law does not prohibit, but specifically endorses the patentability of new combinations of old elements:

*As this court has stated, ‘virtually all inventions are combinations of old elements.’ Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be an ‘illogical and inappropriate process by which to determine patentability.’*

*In re Rouffet*, 47 USPQ3d 1453 (Fed. Cir. 1998).

Applicants’ representative believes that this and other patent law precedent remains, requiring that a rejection based on obviousness must contain a reasoned rationale that would be considered something more than a mere reconstruction of elements of the prior art made with the benefit of and based solely on the content of an Applicants’ own specification and claims. In

view of the lack of such rationale in the stated rejection, the rejection is believed to be legally insufficient and should be withdrawn.

*The Claims Would Not Have Been Obvious Over the Cited Reference*

Aside from the lack of legitimate grounds of rejection presented in the Office action, looking at the references themselves, no information found in either reference -- taken alone or in combination -- provides reason to combine the different features of the references to arrive at the subject matter of the pending claims. The cited prior art can even be said to teach away from the claimed subject matter.

The Salama reference contains no mention of applying its drainage catheter to an anastomosis procedure.

The Seiba reference teaches away from the claimed design of an anastomosis device that combines features of a catheter body and tissue approximating structure on the catheter body, as claimed. Contrary to the pending claims, the Seiba reference requires needle structure placed on an expandable stent, and that the expandable stent not be part of the described “Delivery Catheter.” To place the needle structure on a catheter body, as recited in Applicants’ claims, goes directly against the necessary design, function, and purpose of the Seiba device and methods, which involve a separable stent and Delivery Catheter to allow delivery of the expandable stent followed by removal of the “Delivery Catheter.”

At paragraph 0025, Seiba recites:

*It is to be understood that the stent device and associated methods of the present invention are applicable to a variety of anastomosis procedures wherein two conduits are to be joined in a manner facilitating fluid flow and patency.*

Additional language at paragraph [0051] of the Seiba reference even more clearly teaches toward a stent, and away from the combined catheter and anastomosis features:

*It is to be further understood that the substantially hollow nature of stent 10 permits introduction of a variety of different surgical tools at any time during or after deployment. Typical devices may include, for example, . . . Foley catheters . . . .*

This language, as well as the entire balance of the Seiba reference, require a stent device delivered to within the body using a “Delivery Catheter” that is then removed from the body. The stent alone functions to hold tissue for anastomosis. Catheter devices are intentionally separate from the stent. The entire teaching at least fails to contemplate the claimed subject

matter of a combination of a drainage catheter equipped with anastomosis functionality, and even teaches away from this combination by intentionally separating the catheter (“Delivery Catheter”) and a drainage catheter (Foley catheter) from an anastomosis functionality (on the stent). As a technical matter, the intentional and necessary separation of the catheter and anastomosis features required by the Seiba reference is contrary to the pending claims and thereby teaches away from the pending claims.

In terms of the problem faced and the solution provided by the prior art, neither cited reference identifies or achieves advantages of the inventive device including ease of use and repositionability of tissue approximating structure, and anastomosis and healing with reduced contact of urine with the site of anastomosis. The Salama device does not provide a device or method that allows both anastomosis and drainage. The Seiba reference offers a device designed to be useful for anastomosis and urine flow from the bladder, but teaches away from the solution discovered and claimed by the present patent applicants. Further, the solution of Seiba, a stent and removable “Delivery Catheter,” does not provide advantages of the presently claimed device, e.g., reduced contact of urine to the anastomosis site.

#### **Claims 4-6, 11 and 14**

Claims 4-6, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salama (U.S. Patent No. 5,306,226) and Seiba (U.S. Publ. No. 20030229364), as applied to Claims 1, 3, and 9 above, and further in view of Biggs et al. (U.S. Patent No. 6,599,311).

Applicants respectfully traverse the rejection. As discussed above, there is no reason to combine the Salama and Seiba references to arrive at the subject matter of Applicants’ independent claims. The Biggs et al. reference does nothing to remedy the shortcomings of the Salama and Seiba references. Biggs et al. describes a method and assembly for lung volume reduction, and more particularly a mechanical lung volume reduction system that includes cords and anchors that pull on portions of a lung to compress the volume of a portion of the lung (col. 1, lines 11-16). There is also no reason to combine the elements of Biggs et al. with the Salama and Seiba references. Nor do those elements remedy any shortcoming with regard to Salama in view of Seiba. Therefore, withdrawal of the applicable rejection is respectfully requested.

Accordingly, it is submitted that presently pending claims 4-6, 11 and 14 are in condition for allowance, and a notice of which is earnestly solicited.

In view of the present amendments and remarks, consideration of the claims as amended, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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